

# **EXHIBIT 12**

2015 WL 7833206

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United States District Court, D. Delaware.

MAYNE PHARMA INTERNATIONAL  
 PTY LTD., Plaintiff,

v.

MERCK & CO., INC., Merck Sharp &  
 Dohme Corp. and N.V. Organon, Defendants.

Civil Action No. 15–438–LPS–CJB

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Signed December 3, 2015

### Attorneys and Law Firms

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## REPORT AND RECOMMENDATION

Christopher J. Burke, UNITED STATES MAGISTRATE  
 JUDGE

\*1 Presently pending before the Court in this patent infringement action is Defendants Merck & Co., Inc., Merck Sharp & Dohme Corp. and N.V. Organon's (collectively, "Merck" or "Defendants") motion to dismiss Plaintiff Mayne Pharma International Pty Ltd.'s ("Mayne" or "Plaintiff") Complaint pursuant to Federal Rule of Civil Procedure 12(b) (6) (the "Motion"). (D.I.10) For the reasons stated below, the Court recommends that Defendants' Motion be GRANTED–IN–PART without prejudice.

## I. BACKGROUND

### A. The Parties

Plaintiff Mayne is an Australian company with its principal place of business in Salisbury South, South Australia. (D.I. 1 at ¶ 1) Mayne is in the business of, *inter alia*, selling pharmaceuticals. (*Id.*)

Defendants Merck & Co., Inc. and Merck Sharp & Dohme Corp. are Delaware companies with principal places of

business in Whitehouse Station, New Jersey. (*Id.* at ¶¶ 2–3) Merck, Sharp & Dohme Corp. is a wholly owned subsidiary of Merck & Co., Inc. (*Id.* at ¶ 3) Defendant N.V. Organon is a company organized under the laws of the Netherlands, with its principal place of business in Oss, Netherlands. (*Id.* at ¶ 4) N.V. Organon, which is a manufacturer of Noxafil® products, is a wholly owned subsidiary of Defendants Merck & Co., Inc. and Merck Sharp & Dohme Corp. (*Id.*)

### B. Procedural Background

On May 29, 2015, Plaintiff commenced this action, asserting that Defendants directly and willfully infringe U.S. Patent No. 6,881,745 (the " '745 patent") entitled "Pharmaceutical Compositions for Poorly Soluble Drugs" through the manufacture, sale and importation of Noxafil products. (D.I.1) On June 5, 2015, Chief Judge Leonard P. Stark referred to the Court for resolution all matters relating to scheduling and any motions to dismiss, stay, and/or transfer venue that are filed in the case. (D.I.5)

In lieu of answering the Complaint, Defendants filed the instant Motion on September 16, 2015. (D.I.10) Briefing on the Motion was completed on October 16, 2015. (D.I.16)

## II. STANDARD OF REVIEW

The sufficiency of pleadings for non-fraud cases is governed by Federal Rule of Civil Procedure 8, which requires "a short and plain statement of the claim showing that the pleader is entitled to relief[.]" Fed.R.Civ.P. 8(a)(2). When presented with a Rule 12(b)(6) motion to dismiss for failure to state a claim, a court conducts a two-part analysis. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir.2009). First, the court separates the factual and legal elements of a claim, accepting "all of the complaint's well-pleaded facts as true, but [disregarding] any legal conclusions." *Id.* at 210–11. Second, the court determines "whether the facts alleged in the complaint are sufficient to show that the plaintiff has a 'plausible claim for relief.'" *Id.* at 211 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678 (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)). In assessing the plausibility of a claim, the court must "construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to

relief.” *Fowler*, 578 F.3d at 210 (quoting *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 233 (3d Cir.2008)).

### III. DISCUSSION

\*2 Defendants' Motion argues that Plaintiff has insufficiently pleaded its claims of direct infringement and willful infringement. The Court will consider these arguments in turn.

#### A. Direct Infringement

35 U.S.C. § 271(a) provides for the cause of action for direct infringement, under which “whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.” 35 U.S.C. § 271(a). A plaintiff pleading a claim of direct infringement must put forward allegations that equal or exceed the level of specificity required by Form 18 of the Federal Rules of Civil Procedure.<sup>1</sup> *In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1334 (Fed.Cir.2012); *McRo, Inc. v. Rockstar Games, Inc.*, Civil Action No. 12–1513–LPS–CJB, 2014 WL 1051527, at \*2 (D.Del. Mar. 17, 2014) (citing *K–Tech Telecommc'ns., Inc. v. Time Warner Cable, Inc.*, 714 F.3d 1277, 1283–84 (Fed.Cir.2013)), *report and recommendation adopted*, 2014 WL 1677366 (D.Del. Apr. 24, 2014). In total, Form 18 requires “(1) an allegation of jurisdiction; (2) a statement that the plaintiff owns the patent; (3) a statement that defendant has been infringing the patent ‘by making, selling, and using [the device] embodying the patent’; (4) a statement that the plaintiff has given the defendant notice of its infringement; and (5) a demand for an injunction and damages.” *K–Tech Telecommc'ns.*, 714 F.3d at 1283 (citation omitted).

Defendants allege that Plaintiffs Complaint does not adequately plead direct infringement because Plaintiff failed to identify which entity is responsible for the alleged infringing activity by lumping together its allegations against the three Defendants. (D.I. 11 at 1, 3–4; D.I. 16 at 4–6); *see also M2M Sols. LLC v. Telit Commc'ns PLC*, Civil Action No. 14–1103–RGA, 2015 WL 4640400, at \*3 (D.Del. Aug. 5, 2015) (noting that a plaintiff cannot satisfy Form 18's pleading requirements regarding a direct infringement claim by “lump[ing]” allegations as to multiple defendants together). In making this argument in their opening brief, Defendants focus exclusively on the content of one allegation found in Plaintiff's Count I asserting direct infringement:

“Defendants have infringed and continue to infringe the 745 patent by making, using, offering for sale or selling within the United States and/or importing into the United States products that infringe one or more claims of the 745 patent, including but not limited to its Noxafil products.” (D.I. 1 at ¶ 15 (*cited in* D.I. 11 at 4))

\*3 Plaintiff responds that it has sufficiently pleaded direct infringement because it has “alleged infringing acts committed by each of the defendants individually, as well as a part of a concerted effort by three corporate entities that are under common ownership and control to infringe Mayne's patent.” (D.I. 14 at 5) In prior sections of its Complaint (the “Parties” and “Jurisdiction and Venue” sections), Plaintiff alleged the following facts relevant to the respective Defendants, (*id.*):

- “N.V. Organon is a manufacturer of Noxafil products.” (D.I. 1 at ¶ 4)
- “N.V. Organon has transacted business with Defendants Merck & Co., Inc. and Merck Sharp & Dohme Corp. with respect to the infringing Noxafil products.” (*Id.* at ¶ 9)
- “N.V. Organon has ... manufactured the infringing Noxafil products for the Defendants Merck & Co., Inc. and Merck Sharp & Dohme Corp. and injected the infringing Noxafil products into the stream of commerce with knowledge that those products will be sold throughout the United States ... for the benefit of Defendants Merck & Co., Inc. and Merck Sharp & Dohme Corp.” (*Id.*)
- “Defendants Merck & Co., Inc. and Merck Sharp & Dohme Corp .... regularly transact business within this judicial district, including sales of the infringing product[.]” (*Id.* at ¶ 8)

Plaintiff's Complaint further alleges that N.V. Organon is a “wholly-owned subsidiary” of Defendants Merck & Co., Inc. and Merck Sharp & Dohme Corp. and “does not have a separate corporate existence other than as a Merck entity[.]” (*Id.* at ¶¶ 4, 9) Merck Sharp & Dohme Corp. is itself alleged to be a wholly owned subsidiary of Merck & Co., Inc. (*Id.* at ¶ 3)

The Court concludes that Plaintiff has sufficiently pleaded direct infringement with respect to Merck & Co., Inc. and Merck Sharp & Dohme Corp. While the allegation in Count I of the Complaint that Defendants focus upon indeed simply refers to “Defendants” collectively, that Count

also incorporates “each of the preceding paragraphs” of the Complaint. (*Id.* at ¶¶ 11, 15) And, as set out above, one of those preceding paragraphs alleges that both of these U.S. based defendants “regularly transact ... sales of the infringing product” in this country, including in Delaware. (*Id.* at ¶ 8) Pursuant to Section 271(a), selling an infringing product (within the United States) constitutes direct infringement. 35 U.S.C. § 271(a). Therefore, the Complaint adequately identifies specific infringing acts of Merck & Co., Inc. and Merck Sharp & Dohme. (*See* D.I. 14 at 5 (explaining that “Mayne has identified that [ ] the defendants are individually responsible for specific infringing acts through their ... sale of the Noxafil products”))<sup>2</sup>

\*4 The Court cannot reach the same conclusion, however, with respect to N.V. Organon. Unlike Merck & Co., Inc. and Merck Sharp & Dohme Corp., N.V. Organon is not located in the United States; it is alleged to be a Dutch company entirely located in the Netherlands. While the Complaint is clear that N.V. Organon (1) is a wholly owned subsidiary of the other two Defendants and (2) manufactures the accused products, Defendants correctly note that “allegations that a foreign defendant has ‘manufactured’ the accused product are not allegations of infringement under 271(a).” (D.I. 16 at 5); *see, e.g., Cybionics, Ltd. v. Golden Source Elecs. Ltd.*, 130 F.Supp.2d 1152, 1163 (C.D.Cal.2001) (“As [Section 271(a)] makes clear, and as the Federal Circuit has recently reiterated, the only activities that are relevant to direct infringement are those activities that take place within the borders of the United States. Extraterritorial activities are irrelevant.”) (citing *Rotec Indus., Inc. v. Mitsubishi Corp.*, 215 F.3d 1246, 1251 (Fed.Cir.2000)); *Tr. of Columbia Univ. in City of N.Y. v. Roche Diagnostics GmbH*, 150 F.Supp.2d 191, 201–02 (D.Mass.2001).

In order to plead a sufficient claim of direct infringement against N.V. Organon, then, Plaintiff must allege facts plausibly identifying sufficient infringing activity by that Defendant that took place within the United States, such as the importation of the accused products into the United States. *Cybionics, Ltd.*, 130 F.Supp.2d at 1166–67; *cf. Nuance Commc'ns, Inc. v. Abbyy Software House*, 626 F.3d 1222, 1233 (Fed.Cir.2010) (a foreign defendant can import products into the United States “within the meaning of [Section] 271(a)”). The “Jurisdiction and Venue” section of Plaintiff’s Complaint does allege that N.V. Organon “injected the infringing Noxafil products into the stream of commerce with knowledge that those products will be sold throughout the United States[.]” (D.I. 1 at ¶ 9 (emphasis added)) But it is

not clear from the Complaint what this is meant to assert; for example, this opaque claim does not state that N.V. Organon itself imported the accused products into the United States. And, as Defendants point out, (D.I. 16 at 4), Plaintiff’s direct infringement allegation in the body of Count I does not clear up the matter of which defendant(s) engage in the importation of Noxafil. Instead, the Count simply alleges that “Defendants have infringed and continue to infringe the 745 patent by making ... and/or importing into the United States products that infringe[.]” (D.I. 1 at ¶ 15)

In a few places, Plaintiff’s briefing also makes reference to its claim that it has alleged a “parent-subsidiary relationship between [parent Merck & Co., Inc. and subsidiary N.V. Organon] where the parent effectively controls the conduct of the subsidiary.” (D.I. 14 at 6) To the extent Plaintiff is asserting that an allegation of this type of “control” solves its pleading problem as to N.V. Organon, the Court disagrees. It is true that a plaintiff can plead facts in a complaint setting out a plausible claim that a foreign parent should be held responsible for the acts of a domestic subsidiary. *M2M Sols. LLC*, 2015 WL 4640400, at \*3.<sup>3</sup> But even if Plaintiff had alleged sufficient facts to plausibly assert that the parent here (Merck & Co., Inc.) should be held responsible for the actions of the subsidiary in question (N.V. Organon) (and the Court is not convinced that it has), this would not affect the outcome. That is because the foreign Defendant in question, N.V. Organon, is the subsidiary, not the parent. And its alleged infringing conduct has not been plausibly alleged to have taken place in the United States. So, even if Plaintiff had shown that Merck & Co., Inc. effectively controlled N.V. Organon’s Netherlands-based, noninfringing acts, the Court does not see how this would put *N.V. Organon* any closer to facing actionable claims of direct infringement in this Court.

\*5 Therefore, the Court finds that Plaintiff’s Complaint does not sufficiently allege direct infringement against N.V. Organon.

### B. Willful Infringement

Defendants also assert that Plaintiff’s willful infringement claim must be dismissed because Plaintiff has alleged no supporting facts in its Complaint. (D.I. 11 at 1, 4–6; D.I. 16 at 1–4) The Court easily agrees.

To prove a case of willful infringement, a patent owner must demonstrate by clear and convincing evidence that the infringer acted despite an “objectively high likelihood that its

actions constituted infringement” and that this “objectively-defined risk ... was either known or so obvious that it should have been known to the accused infringer.” *In re Seagate Tech., LLC*, 497 F.3d 1360, 1371 (Fed.Cir.2007). At the pleading stage, a plaintiff must plead facts giving rise to at least a showing of objective recklessness regarding the infringement risk. *See, e.g., IpVenture Inc. v. Lenovo Grp. Ltd.*, Civil Action No. 11–588–RGA, 2013 WL 126276, at \*2 (D.Del. Jan. 8, 2013); *MONEC Holding AG v. Motorola Mobility, Inc.*, 897 F.Supp.2d 225, 236 (D.Del.2012); *St. Clair Intellectual Prop. Consultants, Inc. v. Hewlett–Packard Co.*, C.A. No. 10–425–LPS, 2012 WL 1134318, at \*2 (D.Del. Mar. 28, 2012).<sup>4</sup> It is not necessary to plead actual knowledge of infringement or the infringement risk, but the complaint must adequately allege factual circumstances in which the patents-in-suit are called to the attention of the defendant. *MONEC Holding AG*, 897 F.Supp.2d at 236; *Hewlett–Packard Co.*, 2012 WL 1134318, at \*2–3. And ultimately, the “complaint must ‘demonstrate[ ] a link between the various allegations of knowledge of the patents-in-suit and the allegations that the risks of infringement’ were either known or were so obvious that they should have been known.” *MONEC Holding AG*, 897 F.Supp.2d at 236 (quoting *Hewlett–Packard Co.*, 2012 WL 1134318, at \*3).<sup>5</sup>

Mayne's Complaint clearly falls short of these pleading requirements. It contains only a single sentence relating to willful infringement: “Upon information and belief, Defendants' infringement has been with knowledge of the 745 patent and has been willful.” (D.I. 1 at 16) The Complaint is devoid of anything that might flesh out the “factual circumstances in which the patent[ ]-in-suit [was] called to the attention of the defendants” or that “giv[e] rise to at least a showing of objective recklessness of the infringement risk.” *Courtesy Prods., L.L.C. v. Hamilton Beach Brands, Inc.*, 73 F.Supp.3d 435, 441 (D.Del.2014) (internal quotation marks and citations omitted).<sup>6</sup> “While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations ..., a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do[.]” *Twombly*, 550 U.S. at 555 (internal quotation marks and brackets omitted). Here, Plaintiff's willful infringement allegations are that kind of “formulaic recitation,” and are therefore insufficient.<sup>7</sup> *See, e.g., HSM Portfolio LLC v. Fujitsu Ltd.*, Civil Action No. 11–770–RGA, 2012 WL 2580547, at \*2 (D.Del. July 3, 2012)

(dismissing willful infringement claims where “[t]he factual support for the allegations of willfulness made in connection with the patents-in-suit are insufficient. There are none.”).

#### IV. CONCLUSION

\*6 For the foregoing reasons, the Court recommends that Defendants' Motion be DENIED as to Plaintiff's claim of direct infringement against Defendants Merck & Co., Inc. and Merck Sharp & Dohme Corp., and GRANTED as to Plaintiff's claim of direct infringement against N.V. Organon. The Court also recommends that Defendants' Motion be GRANTED regarding Plaintiff's claim of willful infringement against all Defendants.

With regard to the claims subject to the grant of the Motion, it is within the Court's discretion to allow leave to amend. *See Foman v. Davis*, 371 U.S. 178, 182 (1962). Because amendment should be allowed “when justice so requires[.]” Fed.R.Civ.P. 15(a)(2), because Plaintiff has requested the ability to do so, (D.I. 14 at 9), and because it is not clear that amendment would cause undue prejudice or would be futile (Defendants do not specifically argue that it would), the Court recommends that Plaintiff be given leave to file an amended complaint to correct the deficiencies outlined above. *See, e.g., Pragmatus AV, LLC v. Yahoo! Inc.*, C.A. No. 11–902–LPS–CJB, 2013 WL 2295344, at \*2 (D.Del. May 24, 2013).

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed.R.Civ.P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed.R.Civ.P. 72(b). The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the district court. *See Henderson v. Carlson*, 812 F.2d 874, 878–79 (3d Cir.1987); *Sincavage v. Barnhart*, 171 Fed.Appx. 924, 925 n.1 (3d Cir.2006).

The parties are directed to the Court's Standing Order for Objections Filed Under Fed.R.Civ.P. 72, dated October 9, 2013, a copy of which is available on the District Court's website, located at <http://www.ded.uscourts.gov>

#### All Citations

Not Reported in Fed. Supp., 2015 WL 7833206



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## Footnotes

- 1 Amendments to the Federal Rules of Civil Procedure taking effect on December 1, 2015 abrogate Rule 84 and the Appendix of Forms, including Form 18. Under the new rules, allegations of direct infringement will be subject to the pleading standards established by *Twombly* and *Iqbal*, requiring plaintiffs to demonstrate a “plausible claim for relief.” The Supreme Court of the United States’ Order that accompanied the submission of the amendments to Congress stated that the amendments “shall take effect on December 1, 2015, and shall govern in all proceedings in civil cases thereafter commenced and, insofar as just and practicable, all proceedings then pending.” Supreme Court of the United States, Order regarding amendments to the Federal Rules of Civil Procedure (Apr. 29, 2015), available at [http://www.supremecourt.gov/orders/courtorders/frcvl5\(update\)\\_1823.pdf](http://www.supremecourt.gov/orders/courtorders/frcvl5(update)_1823.pdf) (last visited Dec. 1, 2015). Here, Defendants do not suggest in their Motion that this change to the Federal Rules would apply retroactively, or that, if it did, that would affect the resolution of this particular Motion. In the absence of any challenge from the movant on this ground, or any argument as to this issue, the Court declines to further address the issue here.
- 2 In contrast, in *M2M Sols. LLC v. Telit Commc’ns PLC*, Civil Action No. 14–1103–RGA, 2015 WL 4640400 (D.Del. Aug. 5, 2015), a case that Defendants cite in arguing that Plaintiff’s allegations are insufficient, (D.I. 11 at 1), the first few allegations of the plaintiff’s complaint simply introduced the defendants, provided the addresses of their principal places of business, and stated that one defendant was a wholly owned subsidiary of the other. *M2M Solutions LLC*, 2015 WL 4640400, at \* 1 & n.1. The complaint in that case, however, did not further link each individual defendant to any specific type of infringing conduct—the remainder of the allegations all “refer[red] to the two [d]efendants as ‘Telit,’ as if both [d]efendants were one entity.” *Id.* at \*1 n.1. The complaint there could not pass muster under Form 18 because it failed to identify which particular defendants were responsible for which infringing products, processes or methods. *Id.* at \*3.
- 3 In such a scenario, the plaintiff would have to allege (1) the existence of a parent-subsidary relationship and (2) facts that justify piercing the corporate veil; one way to satisfy the latter requirement is to demonstrate the existence of an agency relationship wherein the parent effectively controls the conduct of the subsidiary. *Id.* (citing *Novo Nordisk v. Caraco Pharm. Labs.*, 450 F.Supp.2d 757, 761 (E.D.Mich.2006)).
- 4 See also *Cloud Farm Assocs., L.P. v. Volkswagen Grp. of Am., Inc.*, C.A. No. 10–502–LPS, 2012 WL 3069390, at \*3 (D.Del. July 27, 2012) (noting that in order to plead a claim of willful infringement, a plaintiff must meet the requirements of Rule 8 and Rule 11(b) of the Federal Rules of Civil Procedure, and must provide a “pleading equivalent to ‘with a knowledge of the patent and of his infringement’”) (citation omitted); *Chalumeau Power Sys. LLC v. Alcatel–Lucent*, Civil Action No. 11–1175–RGA, 2012 WL 6968938, at \*2 (D.Del. July 18, 2012) (facts alleged regarding willfulness claim must meet *Iqbal* plausibility standard).
- 5 Where, as here, a plaintiff has not sought a preliminary injunction, its willfulness claim must at least be based in part on the accused infringer’s pre-filing conduct and cannot be based solely on post-filing conduct. See *Softview LLC v. Apple Inc.*, Civ. No. 10–389–LPS, 2012 WL 3061027, at \*8 (D.Del. July 26, 2012) (citing *In re Seagate*, 497 F.3d at 1374).
- 6 Plaintiff provides some additional facts with respect to these elements in its answering brief, explaining that “Merck has been on notice that its Noxafil products infringe [the asserted patent] since at least August 2014, when Mayne sent a letter to Merck regarding the 745 patent and Merck’s Noxafil products[,]” and that since that date, the parties have communicated numerous times about Defendants’ alleged infringement. (D.I. 14 at 1–2) However, the Court will not consider these additional facts in assessing the sufficiency of Plaintiff’s willful infringement claim because they are not found in Plaintiff’s Complaint. (D.I. 16 at 1); see also *Pa. ex rel. Zimmerman v. PepsiCo, Inc.*, 836 F.2d 173, 181 (3d Cir.1998) (explaining that “[i]t is axiomatic that the

complaint may not be amended by the brief[ ] in opposition to a motion to dismiss”) (citation omitted); *M2M Sols. LLC*, 2015 WL 4640400, at \*3.

- 7 Plaintiff cites, *inter alia*, to decisions authored by Chief Judge Stark that find willful infringement claims to have been sufficiently pleaded, and asserts that those cases involved similar allegations to those at issue here. (D.I. 14 at 6–7) But these cases are plainly distinguishable, in that the complaints at issue there contained actual facts in support of willful infringement. (D.I. 16 at 2–4) For instance, in *Cloud Farm Assoc. L.P. v. Volkswagen Grp. of Am.*, Civ. No. 10–502–LPS, 2013 WL 3353858 (D.Del. July 2, 2013), the plaintiff attached to its complaint a pre-suit letter from the company's patent attorney to another company which (1) copied the defendant; (2) referenced the asserted patent; (3) indicated that the defendant distributed the accused infringing products in the United States and (4) urged the recipient to “consider the necessity for a license under the subject patent.” *Cloud Farm Assoc. L.P.*, 2013 WL 3353858, at \*2 (internal quotation marks and citation omitted). And in *St. Clair Intellectual Prop. Consultants, Inc. v. Hewlett–Packard Co.*, C.A. No. 10–425–LPS, 2012 WL 1134318 (D.Del. Mar. 28, 2012), this Court found that a complaint sufficiently alleged willful infringement where it (1) “detail[ed] numerous factual circumstances in which the patents-in-suit were called to the attention of [defendants];” and (2) “list[ed] explicit instances where [the defendant] was aware of both the patents-in-suit and that it was either practicing or contemplating practicing technologies related to the patents-in-suit.” *St. Clair*, 2012 WL 1134318, at \*3.

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